

Non-technical Abstract for HVTN 061:

The development of a safe and effective vaccine to prevent HIV infection is a global health priority. Wyeth Research is developing a combination HIV vaccine regimen. One vaccine is made from DNA, genetic material containing part of an HIV gene. This vaccine is called HIV-1 *gag* DNA. Another kind of vaccine is made with parts of proteins that mimic limited portions of HIV, and is called HIV CTL MEP. These vaccines are given with adjuvants, substances used to stimulate the immune system to increase the response to the vaccines. It is hoped that using these vaccines one after another in a combination vaccine approach may be able to raise enough immunity to protect against HIV. The study will involve up to 96 healthy adult participants who do not have HIV. These participants will already have participated in an HIV vaccine trial (HVTN Protocol 056) that tested HIV CTL MEP vaccine, with one or two adjuvants. In HVTN 061, some people will get the same vaccine they received in HVTN 056 (HIV CTL MEP), some will receive HIV-1 *gag* DNA vaccine, and people who received a salt water solution (placebo) without any HIV vaccine in HVTN 056 will receive placebo again. Participants will not know what they received in this trial or HVTN 056 until this trial is finished. The multicenter, randomized, placebo-controlled, double blinded study will be done at 7 sites. None of the vaccines can cause HIV infection or AIDS.

Similar vaccines have been tested in monkeys, and the effect of the vaccines on the immune system could be measured in the blood. The two different kinds of vaccine have not previously been given to the same animal. In experiments of each of the vaccines given separately to animals, the vaccines were safe and the effects of the vaccine on the immune system could be measured. The main purpose of the present study is to make sure that the vaccines and the adjuvants are all safe and cause no serious or bothersome side effects.